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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,627	01/20/2004	Kevin John Brown	2775/107	8255

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EXAMINER	
ARTMAN, THOMAS R	

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/760,627	BROWN ET AL.
	Examiner	Art Unit
	Thomas R. Artman	2882

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *14 ~~June~~ July 2004*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 13 is objected to because of the following: it appears as though claim 13 should depend from claim 8, rather than claim 7, in order to eliminate redundancy.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulkes (US 6,721,386 B2) in view of Edic (US 6,353,653 B1) and Rasche (US 6,865,248 B1).

Regarding claims 1 and 8, Bulkes discloses a method and apparatus of CT scanning in which cardiac correlation techniques are applied to acquired projection images (col.5, lines 1-42).

Bulkes does not specifically disclose that the device performs cone beam CT scanning that provides 2-D projection images. Bulkes uses fan beam CT scanning, which requires different image reconstruction techniques. However, it is clear to one skilled in the art that the method of applying correlation techniques to select a particular set of

projection data for reconstruction is independent of the type of reconstruction method. The method selects *what* projection images are to be reconstructed, not *how* to reconstruct them.

More specifically, Edic teaches a method of physiological gating to reduce motion artifacts in CT scanning where cone beam CT scanning can be used in lieu of fan beam scanning in order to further reduce motion artifacts, further taking into account the differences in reconstruction methods as is known in the art (col.3, line 59, through col.4, line 9). Cone beam CT scanning takes a 2-D image, rather than the 1-D slice taken by fan beam CT scanning, and is therefore a faster scanning method for acquiring the necessary projection data over a given region of a patient. The speed helps to further reduce motion artifacts as well as reduce the total radiation dose to the patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Bulkes to use cone beam CT scanning in order to image the patient more efficiently and safely as taught by Edic.

Further regarding claims 1 and 8, Bulkes does not specifically disclose that the correlation techniques are respiratory correlation techniques. Bulkes discusses motion artifacts caused by cardiac cycles, not respiratory cycles. However, it is known to one skilled in the art that both cardiac and respiratory cycles cause image artifacts in reconstructed CT images, and therefore need to be correlated. Further, one skilled in the art would readily recognize that the method of Bulkes is equally applicable to correlating either or both cyclic physiological phenomena.

More specifically, Rasche teaches a CT scanning correlation technique for reducing cardiac motion artifacts, and further shows that the same correlation methods are useful for correlating respiratory motion (col.6, lines 22-52). This is particularly important in circumstances where the patient, whether due to age or physical condition, cannot hold their breath, which is a common mechanism that Bulkes relies upon in order to remove respiratory motion artifacts.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Bulkes to correlate respiratory motion in order to reduce motion artifacts caused by the patient's respiratory cycle, as well as the cardiac cycle, as taught by Rasche.

With respect to claims 2 and 9, Bulkes further discloses that the phase of the patient's motion is continuously monitored (col.5, lines 1-15).

With respect to claims 3 and 10, Bulkes further discloses that the projection images that have comparable phases are selected from a complete data set upon completion of the acquisition of projection images and are used to reconstruct the volume data (col.5, lines 16-42).

Claims 4, 5, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulkes, Edic and Rasche, as applied to claims 2 and 9, respectively, in view of Hsieh (US 6,480,560 B2).

With respect to claims 4 and 11, neither Bulkes nor Edic nor Rasche specifically disclose that the breathing phase is determined by a feature in the projection image.

Hsieh specifically teaches the practice of measuring the mechanics of a feature (in this case, the heart) through analysis of the projection images in order to determine the phase of the cyclic motion and then use the phase to correlate projection images of common phase (see at least Abstract and Fig.3). In this way, a more accurate phase is measured rather than through measurements from other monitors (similar to that of Bulkes and Rasche) without the need for any additional monitors (col.2, lines 1-8 and lines 39-44). A more accurate phase determination allows for a more accurate reconstructed image due to improved correlation for selecting the projection data to reconstruct with respect to the phase of the motion.

Although Hsieh teaches the method specifically for determining the cardiac phase, it is clear from the teachings of Rasche that respiratory phase must also be considered. More specifically, the diaphragm, which is feature useful for determining the breathing phase, is monitored by Rasche.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Bulkes to determine the patients' breathing phase from a feature in the projection image in order to improve the accuracy of the phase determination, which in turn improves the image quality since a more accurate phase allows more accurate selection of in-phase projections for reconstruction purposes, as taught by Hsieh.

With respect to claims 5 and 12, none of Bulkes, Edic, Rasche and Hsieh specifically disclose the practice of tracking the position of the diaphragm in projection images in order to determine the respiratory phase of the patient.

However, the teachings of Rasche and Bulkes specifically state that, in order to measure cardiac phase accurately, the motion of the heart must be monitored since that organ is the source of the motion.

Hsieh further teaches that the most accurate way to measure the actual cardiac phase is to derive the phase from projection images of the heart itself.

Rasche further teaches that, in order to measure a respiratory phase accurately, the motion of the diaphragm must be monitored since that organ is the source of the motion.

Therefore it follows from the above teachings that it would have been obvious to one of ordinary skill in the art at the time the invention was made for Bulkes to measure the respiratory phase directly through images of the diaphragm, since Rasche recognizes that the position of the diaphragm should be monitored in order to accurately measure a breathing phase, and Hsieh recognizes that a more accurate way to measure the phase of physiological motion is directly through projection images of the organ causing the motion.

Claims 1, 2, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasche in view of Edic.

Regarding claims 1 and 8, Rasche discloses a method and apparatus of CT scanning in which respiration correlation techniques are applied to the acquired projection images (col.6, lines 22-52).

Rasche does not specifically disclose the use of cone beam CT, which results in 2-D projection images. Rasche appears to use fan beam CT scanning, which requires different image reconstruction techniques. However, it is clear to one skilled in the art that the method of applying correlation techniques to acquiring a particular set of projection data for reconstruction is independent of the type of reconstruction method. The method of Rasche selects *when* to take the projection images, not *how* to reconstruct them.

More specifically, Edic teaches a method of physiological gating to reduce motion artifacts in CT scanning where cone beam CT scanning can be used in lieu of fan beam scanning in order to further reduce motion artifacts, further taking into account the differences in reconstruction methods as is known in the art (col.3, line 59, through col.4, line 9). Cone beam CT scanning takes a 2-D image, rather than the 1-D slice taken by fan beam CT scanning, and is therefore a faster scanning method for acquiring the necessary projection data over a given region of a patient. The speed helps to further reduce motion artifacts as well as reduce the total radiation dose to the patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Rasche to use cone beam CT scanning in order to image the patient more efficiently and safely as taught by Edic.

With respect tot claims 2 and 9, Rasche further discloses that the phase of the patient's breathing is monitored continuously during acquisition.

Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasche and Edic, as applied against claims 2 and 9 above, respectfully, in view of Bulkes.

With respect to both claims, Rasche does not specifically disclose the practice of selecting projection images with common breathing phases from a complete data set after acquisition of the complete data set for reconstructing an image of the object of interest. Rasche performs the typical gating technique where the phases are monitored in order to instruct the CT scanner when to take projection images as a function of phase.

Bulkes teaches the practice of continuously monitoring the phase of a patient's motion while simultaneously taking a complete set of projection data such that any phase of the heart can be accurately imaged. This is because the projection data is time stamped with the phase information from the ECG and motion detection monitors, and the images can be selected by common phase and reconstructed as desired (col.5, lines -42). Further, the accuracy of Bulkes method is improved over that of Rasche because the CT scanning adjustments to the measured respiratory cycle are not as accurate as being able to select time-stamped images after acquisition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Rasche to select projection images with common breathing phases from a complete set of data for a more accurate reconstruction of images of the object of interest as taught by Bulkes.

Claims 4, 5, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasche and Edic, as applied against claims 2 and 9 above, respectively, in view of Hsieh.

With respect to all the above claims, Rasche does not specifically disclose the practice of determining the breathing phase from a feature in the projection image, particularly that of the diaphragm.

Hsieh specifically teaches the practice of determining a cardiac phase by directly imaging the heart and deriving the phase from the heart in the projection images (col. col.2, lines 1-8 and lines 39-44). This is more accurate since it directly measures the heart's position rather than indirectly measuring the heart's motion through the ECG signals of Rasche, and thus does not require the additional equipment for such monitoring. A more accurate phase determination allows for a more accurate reconstructed image due to improved correlation for selecting the projection data to reconstruct with respect to the phase of the motion.

Hsieh does not, however, determine respiratory phase from images of the diaphragm. Hsieh is concerned primarily with heart-induced motion artifacts and therefore determines the cardiac phase.

The teachings of Rasche specifically state that, in order to measure respiratory phase accurately, the motion of the diaphragm must be monitored since that organ is the source of the motion, just as the heart is the source of cardiac cycle induced motion (col.6, lines 22-52).

Therefore it follows from the above teachings that it would have been obvious to one of ordinary skill in the art at the time the invention was made for Rasche to measure

the respiratory phase directly through images of the diaphragm, since Hsieh recognizes that a more accurate way to measure the phase of physiological motion is directly through projection images of the organ causing the motion.

Claims 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulkes, Edic and Rasche, as applied to claims 1 and 8 above, respectfully, in view of Mostafavi (US 6,937,696 B1).

With respect to both claims, neither Bulkes nor Edic and Rasche specifically disclose the practice of using visual or audible prompts provided for the patient's breathing. Bulkes merely states that the patient is instructed to carry out a series of breath-holds during the scanning procedure.

Mostafavi specifically teaches the practice of using audible and visual prompts for the patient's breathing (col.3, lines 29-44). This provides improved control over the position of the region of interest for more accurate imaging and positioning of the procedure system.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use audible and/or visual prompts in order to improve the correlation with the image data and the patient's breathing cycle as taught by Mostafavi.

Claims 1, 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanematsu (US 6,385,288 B1) in view of Edic and Mostafavi.

Regarding claims 1 and 14, Kanematsu discloses a method and apparatus that applied respiratory correlation techniques to acquired projection images (col.3, lines 55-59; col.11, lines 35-58).

Kanematsu does not specifically disclose cone beam CT scanning. Kanematsu appears to use fan beam CT scanning, which requires different image reconstruction techniques.

Edic teaches a method of physiological gating to reduce motion artifacts in CT scanning where cone beam CT scanning can be used in lieu of fan beam scanning in order to further reduce motion artifacts, taking into account the differences in reconstruction methods as is known in the art (col.3, line 59, through col.4, line 9). Cone beam CT scanning takes a 2-D image, rather than the 1-D slice taken by fan beam CT scanning, and is therefore a faster scanning method for acquiring the necessary projection data over a given region of a patient. The speed helps to further reduce motion artifacts as well as reduce the total radiation dose to the patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kanematsu to use cone beam CT scanning in order to image the patient more efficiently and safely as taught by Edic.

Further regarding claim 14 and with respect to claim 7, Kanematsu does not specifically disclose delivering the therapeutic radiation at times correlated with the patient's breathing cycle. Kanematsu uses the correlated image data to move the patient table with a constant therapeutic radiation beam.

Mostafavi teaches the practice of gating the therapeutic radiation in correlation with the breathing cycle of a patient (col.1, lines 50-67; col.2, lines 21-39). In this way, the therapeutic radiation is less likely to harm surrounding healthy tissue than risking the delay of moving the patient undergoing therapeutic radiation constantly to keep up with the respiration cycle.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kanematsu to gate the therapeutic radiation in correlation with the patient's breathing cycle in order to more safely treat the patient, as generally taught by Mostafavi.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mostafavi (US 6,621,889 B1) teaches gated therapeutic radiation techniques. Lin (US 5,579,358) realigns/rescales successive CT images based upon the movement of the specific feature being imaged. Sembritzki (US 6,650,726 B2) corrects projections with complementary CT data; does not select particularly projections. Takagi (US 6,470,066 B2) teaches the practice of physiologically gating CT image acquisition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas R. Artman whose telephone number is (571) 272-2485. The examiner can normally be reached on 9am - 5:30pm Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thomas R. Artman
Patent Examiner TRA

Craig E Church

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